OCT 2 2 2010

K102124

510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of 21 CFR Part 872.1800.

Date

July 23, 2010

Manufacturer

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VATECH America.
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Contact person: Mr. Dave Kim

Trade/Proprietary Name:

PaX-Reve3D Plus

Common Name:

Dental Computed Tomography X-ray System

Classification Name:

X-ray, Tomography, Computed, Dental (21CFR 892.1750, Product code OAS, Class2)

Description:

PaX-Reve3D Plus is a diagnostic imaging system which consists of multiple image acquisition modes; panorama, cephalometric, and computed tomography for implantation. Specifically designed for dental radiography of the oral and craniofacial anatomy, PaX-Reve3D Plus is equipped with extra-oral x-ray detector, panoramic radiography with an extra-oral x-ray tube, cephalometric radiography and computed tomographic radiography.
The computed tomography is a system based on CMOS digital X-ray detector. CMOS CT detector is used to capture scanned images in 3D for obtaining diagnostic information for craniofacial surgery or other treatments. The device can also be operated as the panoramic and cephalometirc dental x-ray system based on CMOS X-ray detector.

Indication for use:

PaX-Reve3D Plus is a computed tomography x-ray system intended to produce panoramic, cephalometric or cross-sectional images of the oral and craniofacial anatomy on a real time basis by computer reconstruction of x-ray image data from the same axial plane taken at different angles. It provides diagnostic details of the anatomic structures by acquiring 360° rotational image sequences of oral and craniofacial area for a precise treatment planning in adult and pediatric care . The device is operated and used by physicians, dentists, and x-ray technicians.

Predicate Device:

Manufacturer	: E-WOO Technology Co., Ltd.
Device	: PaX-Reve3D
510(k) Number	: K090171 (Decision Date – 4/30/2009)

Substantial Equivalence:

The PaX-Reve3D Plus described in this 510(k) has the same intended use and similar technical characteristics as PaX-Reve3D of E-WOO Technology Co., Ltd.

Characteristic	**Proposed** **Vatech Co., Ltd.** ***PaX-Reve3D Plus***	**Predicate** **E-WOO Technology Co., Ltd.** ***PaX-Reve3D***

510(k) number	-	K090171
Indications for use	PaX-Reve3D Plus is a computed tomography x-ray system intended to produce panoramic, cephalometric or cross-sectional images of the oral and craniofacial anatomy on a real time basis by computer reconstruction of x-ray image data from the same axial plane taken at different angles. It provides diagnostic details of the anatomic structures by acquiring 360° rotational image sequences of oral and craniofacial area for a precise treatment planning in adult and pediatric care . The device is operated and used by physicians, dentists, and x-ray technicians.	PaX-Reve3D is Computed Tomography X-Ray System. Real time - image acquisition. Especially, advanced digital imaging process allows considerably efficient diagnosis, all kind of information management, real-time sharing of image information on network. Furthermore PaX-Reve3D is equipped with the Flat Panel Detector, CT sensor to capture a 3D X-ray Computed tomography scanned image.
Performance Specification	Panoramic, cephalometric and computed tomography	Panoramic, cephalometric and computed tomography
Input Voltage	110V/230V~	110V/220V~
Tube Voltage	50-100 kV	40-90kV
Tube Current	2 ~10 mA	2-10mA
Focal Spot Size	0.5 mm	0.5mm
Exposure Time	0.5-24 s (Various)	0.5s-24s (Various)
Size of Imaging Volume	15 x 15 cm 12 x 8 cm 8 x 6 cm 5 x 5 cm	14 x 12 cm 10 x 6 cm 8 x 6 cm 5 x 5 cm
Slice Width	0.1mm min.	0.1mm min.
Total Filtration	2.8mmAl	2.8mmAl
Pixel Resolution	2.5 lp/mm - CT	2.5 lp/mm - CT
	5 lp/mm – Panorama	4.5 lp/mm – Panorama
	3.94 lp/mm – Cephalometric	3.94 lp/mm – Cephalometric
Pixel Size	200 ㎛ - CT	200 ㎛ - CT
	100 ㎛ - Panorama	96 ㎛ - Panorama
	127 ㎛ - Cephalometric	127 ㎛ - Cephalometric

Image Receptor	CT with Flat Panel Detector	CT with Flat Panel Detector
Chin Rest	Equipped Headrest	Equipped Headrest
Performance Specification	Computed tomography	Computed tomography
Mechanical	Compact design	Compact design
Electrical	LDCP logic circuit	LDCP logic circuit
Software	DICOM 3.0 Format compatible	DICOM 3.0 Format compatible
Anatomical Sites	Maxillofacial	Maxillofacial

The indications for use, material, form factor, performance, and safety characteristics between PaX-Reve3D Plus and the predicate device are the same. The primary difference is cosmetic, structure and component used only. Accordingly we can claim the substantially equivalence of PaX-Reve3D Plus to the predicate device.

Safety, EMC and Performance Data:

Electrical, mechanical, environmental safety and performance testing according to standard IEC 60601-1 (A1+A2, 1995), IEC 60601-1-3(Ed.1, 2006), IEC 60601-2-7 (1998), IEC 60601-2-28 (Ed.1, 1993), IEC 60601-2-32 (Ed.3, 2007), and IEC 60601-2044 (Ed.2+A1, 2002) was performed, and EMC testing were conducted in accordance with standard IEC 60601-1-2.

Non-clinical & Clinical considerations according to FDA Guidance "Guidance for the Submissions of 510(k)'s for Solid State X-ray Imaging Devices" was performed.
All test results were satisfactory.

Conclusion:

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807 and based on the information provided in this premarket notification. Vatech Co., Ltd. concludes that PaX-Reve3D Plus is safe and effective and substantially equivalent to predicate device as described herein.

END

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

VATECH Co., Ltd.
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OCT 2 2 2010

Re: K102124
Trade/Device Name: Dental Computed tomography X-ray system
Regulation Number: 21 CFR 872.1800
Regulation Name: Extraoral source x-ray system
Regulatory Class: II
Product Code: MUH
Dated: July 23, 2010
Received: July 29, 2010

Dear Mr. Kim:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

David G. Brown, Ph.D.
Acting Director
Division of Radiological Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(K) Number (if known): K102124

DCT 2 2 2010

Device Name: PaX-Reve3D Plus

Classification: Dental Computed tomography X-ray system

Indications for Use:

PaX-Reve3D Plus is a computed tomography x-ray system intended to produce panoramic, cephalometric or cross-sectional images of the oral and craniofacial anatomy on a real time basis by computer reconstruction of x-ray image data from the same axial plane taken at different angles. It provides diagnostic details of the anatomic structures by acquiring 360° rotational image sequences of oral and craniofacial area for a precise treatment planning in adult and pediatric care . The device is operated and used by physicians, dentists, and x-ray technicians.

Prescription Use ✓ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, ~~Office of Device Evaluation (ODE)~~ DIVD

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

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